



*The Heart of a
Healthy Community*

How to write a Protocol Summary

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Protocol Summary

- Every research application that is submitted requires a Protocol Summary which should include details of the study you are wishing to conduct
- The IRB has created a general outline divided into several sections of what you should include in your Protocol
- The Protocol Summary is your chance to elaborate and include all of the necessary information in order for you to conduct your research. This will help the reviewers of your application better understand the purpose of your research

Section I: Be sure to include the title of your study as well as all investigators participating in your study

Section II: This should be your hypothesis or your purpose of conducting the research

Section III: What reasons led you to wanting to conduct this research project

Section IV: What type of study are you wishing to conduct

Section V: Details on who, when, where, etc. (Be Specific)

Principal Investigators are required to prepare a summary of the protocol to include the following:

- I. Full title of the protocol, Investigators
- II. Introduction: Objectives, purpose of the study, research question, hypothesis 0
- III. Background/Literature Review- summarize relevant literature that led you to research problem and approach.
- IV. Study type: Retrospective or Prospective
- V. Study Information: location, start and stop dates, type of research (Biomedical, Drug, Biologic, Device, Tissue/Blood specimen, other), inclusion and exclusion criteria (should be justified in the background information/literature review), subject recruitment and screening (number of subjects, age, gender, English speaking, subject materials, promotional advertising (promotional advertisements used for recruiting subjects must be submitted to the ARMC-IRB for review and approval), etc.

Section VI: In this section you will want to be specific of the consent process as it pertains to your study. Be sure you are considerate of privacy and who will have access to these records

VI. Consent Process: Specific description of informed consent process to include—but not limited to: who, how, training, when, where, considerations, privacy and time for decision-making/discussion, consent capacity determination (who and how); Method of subject identification and randomization: coding system, subject randomization/group selection process; Privacy of Medical and Research Records information/medical records, Medical Release forms, HIPAA compliance/authorization form

‘Identifiers of our single patient are strictly limited to medical record number, ethnicity, age and sex, along with associated clinical data. All published poster presentations, abstracts and papers will be de-identified, with all names, medical record numbers and any other identifying material removed. Patient’s age, sex and race will be used in publication for educational purposes. Only the principal investigator, co-investigator and research coordinator will have access to the data that is obtained. Medical records and presentation documents will be kept within an encrypted password protected file on a password protected computer that is accessible only to the investigators involved in the study’

Section VII: The study design should include the procedures in which you are collecting data, this is based on your study type, usually Prospective

VII. Study Design and Data Collection: Description of interventional procedures and data collection procedures: to include lab evals, tests, specimen amounts and schedules, clinical assessments/schedule/follow up procedures, case report forms, data collection forms (with description of subject codes), study instruments, rating scales, interview guides. Please include any additional information that will assist the ARMC-IRB in the review of your protocol.

- a. If an Investigational New Drug (IND) is involved, provide the following information: (1) name of drug, (2) source of drug, (3) dosage and schedule of administration, (4) status with Food and Drug Administration and IND#, (5) review of animal studies and previous human studies, (6) reported side effects.
- b. For an approved drug used in an experiment, provide similar information: (1) name, (2) source, (3) dosage, (4) how administered, (5) side effects.
- c. If an Investigational Device (ID) is involved, provide the following information: (1) name of device, (2) manufacturer, (3) status with Food and Drug Administration and ID#, (4) review of animal studies and previous human studies, (5) reported adverse effects.

Section VIII: This will include your post research plan for statistical analysis of the data found

Section IX: The risks and benefits vary depending on the study type. Retrospective studies usually have a less than minimal risk because there is no patient interaction, whereas Prospective studies have a minimal or greater than minimal risk because there may be some kind of testing or survey involvement

VIII. Data Analysis: plans for statistical analysis of data when appropriate

IX. Risks/Benefits: assess potential risks to subjects, benefits either direct or indirect by adding to body of knowledge.

- a. Less than minimal risk: research in which there is no known physical, emotional, psychological, or economical risk. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.).
- b. Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- c. Greater than minimal risk: research procedures that may include risk beyond that ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, biologics or medical devices, stressful psychological testing, use of special populations). This research requires some benefit analysis comparable to the risk and full review by the IRB.

Section X: This only applies to your study if there is a sponsor or a fund source where subjects may be compensated

Section XI: Use APA format to include all of your references used

X. Compensation/Funding Source:
Note if subjects will be compensated, if so, how much. Any funding source should be indicated in the protocol and the application.

XI. References in the following format:
a. Doe, John. *Article Title*. Journal of Medicine. Date etc.